

Appl. No. : 10/669,951
Filed : September 24, 2003

REMARKS

The claim amendments and remarks herein are responsive to the Office Action dated December 14, 2006. Claims 1-25 and 27-38 are pending. Applicant has canceled Claim 26 without prejudice.

Claim Rejections¹

Rejection Under 35 U.S.C. § 102

The Examiner rejected Claims 1-11 and 16-38 under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 6,224,631 to Kohrs.

Claims 1-11 and 16, 17 and 19-25

The Examiner rejected Independent Claims 1, 18 and 26 over Kohrs. Applicant has canceled Claim 26 without prejudice. Applicant has amended Claim 1 to recite:

wherein said first and second bone cutting surfaces comprise a leading edge adapted for straight cutting as the implantable stabilizing device is advanced between adjacent vertebrae;

wherein said first and second bone cutting surfaces comprise a horizontal edge adapted for rotational cutting as the implantable stabilizing device is rotated between said adjacent vertebrae; and

wherein a width between the first bone cutting surface and the second bone cutting surface is adapted to hold harvested bone.

Independent Claims 1 and 18 are patentable over the cited art. The cutting surfaces disclosed in Kohrs are essentially parallel threads oriented perpendicular to the long axis of a "screw" or support member with two cut-outs along its length (thus providing a diminished profile). According to Kohrs, the device can be easily inserted between two end plates when the cut-outs are oriented parallel to the endplates. According to Kohrs, the device is inserted and turned through 90 degrees thereby causing the body to distract the endplates and aligning the threads with the endplate such that rotation causes scoring and endplate bone removal.

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By contrast, Applicant's Claims 1 and 18 recite a leading edge on the first and second bone cutting members. Accordingly, when Applicant's device² is driven between the adjacent endplates the leading edge cuts across and through the lower endplate portion of the vertebral body. Thereafter, upon rotation the horizontal edge on the same blade can further cut or shear a second or perpendicular direction as the harvested endplate is rotated. Thus, with Applicant's device, no distraction is required. Moreover, because Applicant's device has corresponding bone cutting members on the opposite surface of the device, the endplate on each of the opposing vertebral bodies is harvested simultaneously. Thus Applicant's device provides for two large opposing portions of endplate bone to be harvested and precisely reoriented as opposed to "bone shavings" that merely fall into the interior of the device taught by Kohrs.

Accordingly, Independent Claims 1 and 18 are patentable over the cited art. Claims 2-17 and 19-25 are also patentable because they depend from an allowable base claim and because they recite independently patentable features. Thus, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 1-25 under 35 U.S.C. § 102(b).

Claims 27-38

The Examiner rejected Claims 27-38 over Kohrs because, according to the Examiner, the method steps "would have been inherently carried out in the operation of the device".

Even assuming *arguendo* that the claimed method steps may occur in the operation of the cited art device, this alone is entirely insufficient to establish inherency. MPEP 2112 (IV) emphasizes:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency,

¹ Applicant's arguments that the pending claims are patentable over the art cited herein is not an admission that the cited art qualifies as prior art. Applicant expressly reserves the right to assert that the cited art is not prior art in the future should the need arise.

² "Applicant's device" refer to preferred embodiments defined by Claims 1 and 18.

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however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)....³

MPEP 2112 (IV) also emphasizes that the BPAI requires the examiner to show that any allegedly "inherent" features necessarily occur in the cited art:

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)...

There is simply no evidence to show that the method steps recited in Applicant's Claims 27-38 are always and necessarily present in the operation of the devices described in the cited art. Accordingly, the Examiner's rejection cannot be maintained. Applicant respectfully requests that the Examiner withdraw the rejection of Claims 27 – 38 under 35 U.S.C. § 102(b).

Rejection Under 35 U.S.C. § 103

The Examiner rejected Claims 12-15 as being obvious over Kohrs in view of US Patent No. 3,527,841 to Wicker. Because Claims 12-15 depend from an allowable base claim (namely, Claim 1), Claims 12-15 are allowable over the cited art. Moreover, Claims 12-15 recite independently patentable features. Thus, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 12-15 under 35 U.S.C. § 103(a).

³ Emphasis added.

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Applicant respectfully asserts that the present application is fully in condition for allowance. *If any matters should remain, the Examiner is invited to contact the undersigned at the telephone number provided below.* Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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